

REMARKS

Applicant appreciates the time taken by the Examiner to review Applicant's present application. This application has been carefully reviewed in light of the Official Action mailed January 15, 2009. Applicant respectfully requests reconsideration and favorable action in this case.

Claims status

Claims 23-28 and 31-53 were rejected. Claims 1-22, 28-30, and 46-53 are cancelled without prejudice or disclaimer. Claims 23-24, 26, 31, 33-34, 36, 38, 40, 42, and 44 are amended. Support for the amendments may be found in the specification at page 5, lines 11-19, and page 14, line 6 – page 15, line 7. No new matter is added. By this amendment, claims 23-27 and 31-45 remain pending.

Rejections under 35 U.S.C. § 102

Claims 23, 24, 26 and 27 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,610,079 ("Li"). The rejection is respectfully traversed.

Although itself has no force of law, the M.P.E.P. restates the following law: "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, for Li to anticipate claims 23, 24, 26, and 27, Li must teach every element of claims 23, 24, 26, and 27. See M.P.E.P. 2131.

Embodiments as claimed in claim 23 are directed to a method of introducing a fluid into a bone, comprising:

- advancing a bone tap into the bone, the bone tap comprising a passage, one or more openings communicating with the passage, and threading located near an end of a body of the bone tap;
- introducing a fluid to the bone through at least one of the openings;
- allowing the fluid to spread to a portion of the bone; and
- introducing a bone fastener into an opening formed by the bone tap.

Claims 24 and 26-27 depend from claim 23. Thus, in embodiments as claimed in claims 23-24 and 26-27, the fluid is introduced to the bone through the bone tap and allowed to spread to a portion of the bone before the introduction of the bone fastener.

Contrastingly, Li teaches a fixation system and method which employs a fastener to fasten tissues together or to connect a tissue to a bone. After the introduction of the bone fastener, a polymer or other fluid is then injected into a passageway or bore of the fastener. This polymer then cures in place, securing the tissues to the fastener. (*See*, Li, Col. 7, line 58-Col. 8, line 12, and Col. 10, lines 1-2.)

Applicant notes that a similar approach is described in U.S. Patent No. 6,565,572 to Chappius, which is incorporated by reference in the above-identified application. (*See*, Specification, page 1, lines 27-31, and page 2, lines 1-2.) Like Li, a fenestrated bone screw that has been cured in place may be difficult to remove should a subsequent procedure be necessary. (*Id.*)

Embodiments as claimed in claim 23 may enjoy several advantages over prior art approaches. Specifically, embodiments as claimed in claim 23 can strengthen and/or stabilize a damaged or otherwise weakened bone before anchoring a bone fastener into the bone. For example, introducing a fluid to the bone through a bone tap (which may have a diameter that is smaller than a bone fastener) and allowing the fluid to spread to a portion of the bone through the opening(s) of the bone tap before a bone fastener is inserted allows the fluid such as a bone cement to begin the curing process which stabilizes and/or strengthens the bone before the bone fastener is inserted in the bone. (*See*, Specification, page 3, lines 1-2, and page 14, line 26-page 15, line 24.) The bone tap may then be withdrawn from the bone before the bone cement completely hardens and, in one embodiment, leaving behind a shape that is complementary to a distal portion of the bone tap. (*Id.*) In one embodiment, after removal of the bone tap from the bone, the bone cement may be allowed additional time to cure. (*Id.*) In embodiments as claimed, many suitable bone fasteners may be used, including standard, non-fenestrated bone fasteners. (*Id.*) Other advantages include during the introduction of the fluid, thread flights on the bone tap may inhibit retrograde backflow of the fluid. (*See*, Specification, page 2, lines 26-27.)

In the Examiner's Response to Arguments section of the Office Action dated January 15, 2009, the Examiner states on page 5 that the "screw or rivet of Li functions as a bone tap since it forms an opening in bone." Applicant respectfully disagrees. A bone tap is a surgical instrument that is separate and distinct from the screw or rivet of Li. A surgeon might use a

bone tap to prepare an opening in a bone during surgery. However, the bone tap is not an implant that is attached to the bone after surgery. The screw or rivet of Li is not a tool and is meant to stay in place after surgery.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.).

In the instant case, Li discloses a fastener that could create a hole in the bone. Li does not disclose a bone tap. However, the claims in the instant application, including claims 23-24 and 26-27, require preparing an opening using a bone tap. At least according to *In re Robertson*, performing the same function of a claim element does not meet the anticipation standard of either expressly or inherently disclosing the claim element. Therefore, Applicant believes that claims 23-24 and 26-27 are clearly patentable over Li.

As a good faith attempt to expedite the prosecution and place the present application in a condition for allowance, claim 23 is amended herein to recite, among others, "removing the bone tap from the opening in the bone," before a bone fastener is introduced. Additionally, claim 24 is amended herein to recite, "wherein the fluid comprises bone cement, wherein the bone cement is allowed to harden at least partially before the bone tap is removed from the opening in the bone formed by the bone tap, and wherein the portion of the bone filled with the bone cement maintains a shape complementary to the distal end of the body of the bone tap following the removal of the bone tap and prior to the introduction of the bone fastener." Applicant believes that Li does not disclose any of these limitations.

For at least the foregoing reasons, claims 23-24 and 26-27 are submitted to be patentable over Li under 35 U.S.C. § 102(e). Accordingly, withdrawal of this rejection is respectfully requested.

Claims 33, 34, 36-38, 40, 42, 44-47, 49 and 51-53 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,622,731 ("Daniel"). The rejection is respectfully traversed. Claims 46-47, 49, and 51-53 are canceled, render the rejection with respect to these claims moot. Claims 34 and 36-38 depend from claim 33. Claims 42 and 44-45 depend from claim 40. Claim 40 contains similar language as claim 33. Accordingly, traversal of the rejection will be collectively addressed as it pertains to claim 33.

Daniel teaches a bone-treatment instrument and method such as those useful for the treatment of a bone tumor, and describes inserting a probe having electrodes into a tumor and applying energy to the electrodes to destroy at least a portion of the nerve receptors located in or adjacent to the tumor to reduce pain associated with the tumor. (See, Daniel, Abstract.)

In the rejection, the Examiner states that Daniel describes an introducer having a threaded section to allow the introducer to be screwed or tapped into bone. Applicant respectfully disagrees and submits that the methods described by Daniel do not stabilize and/or strengthen a portion of a bone prior to the introduction of a bone fastener. The methods described by Daniel do not involve introducing a fluid into a bone through a passage in a bone tap or inserting a bone fastener into the opening in the bone.

Daniel seems to be concerned with injecting a polymer into a tumor mass in a bone and hardening the polymer to repair the bone. (See, Daniel, Col. 2, lines 50-62.) To this end, Daniel describes piercing tissue with an introducer and then deploying one or more energy delivery devices into a tumor mass. (See, Daniel, Col. 10, lines 1-9.) The introducer may have apertures to provide irrigation of a threaded section, and Daniel teaches that the fluids used for the screwing and drilling operations can include cooling fluids and electrolytic and chemotherapeutic fluids. (See, Daniel, Col. 22, lines 37-62.) The introducer may also have one or more lumens for advancing an electrode into the bone mass. (See, Daniel, Col. 23, lines 37-48.) After the opening is prepared, an electrode with lumens for fluid delivery can be inserted in the opening and that fluids introduced through the lumens may include conductivity enhancing fluids, electrolytic fluids, saline solutions, cooling fluids, cryogenic fluids, gases, chemotherapeutic agents, medicaments, gene therapy agents, phototherapeutic agents, contrast agents, infusion media and combinations thereof. (See, Daniel, Col. 12, lines 20-29.)

However, Daniel is introducing fluids during the drilling process that are intended to cool the bone and/or to prevent damage to the bone, introducing fluids into the tissue to improve the performance of the electrode, and then operating the electrode to repair the bone. Daniel is silent as to whether a bone fastener would or even could be inserted into the bone.

In the Examiner's Response to Arguments section of the Office Action dated January 15, 2009, the Examiner states on page 5 that "the introducer 292 [of Daniel] functions as a bone tap." Applicant respectfully disagrees for similar reasons as stated above with respect to the Examiner's statement that the "screw or rivet of Li functions as a bone tap since it forms an opening in bone." Again, the fact that the introducer of Daniel may perform a function of a bone tap is not sufficient to establish that Daniel expressly or inherently discloses a bone tap as required by the claims in the present application.

For at least the foregoing reasons, claims 33, 34, 36-38, 40, 42, and 44-45 are submitted to be patentable over Daniel under 35 U.S.C. § 102(e). Accordingly, withdrawal of this rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claim 25 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Li in view of U.S. Patent No. 6,599,293 ("Tague"). Claims 28, 31 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Li. Claims 35 and 43 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel in view of Tague. Claims 39 and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Daniel. Reliance is placed on *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) for the patentability of claims 25, 28, 31, 32, 35, 39, 41, and 43 as they depend from claims 23, 33, and 40. Applicant respectfully submits that the deficiencies of Li or Daniel are not met by Tague, Li, or Daniel, either alone or in combination. Therefore, design choices notwithstanding, the cited references, alone or in combination, do not render Claims 23, 33, and 40 obvious. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicant has now made an earnest attempt to place this case in condition for allowance. Other than as explicitly set forth above, this reply does not include any acquiescence to statements, assertions, assumptions, conclusions, or any combination thereof in the Office Action. For the foregoing reasons and for other reasons clearly apparent, Applicant respectfully requests full allowance of Claims 23-28 and 31-45. The Examiner is invited to telephone the undersigned at the number listed below for prompt action in the event any issues remain.

The Director of the U.S. Patent and Trademark Office is hereby authorized to charge any fees or credit any overpayments to Deposit Account No. 50-3183 of Sprinkle IP Law Group.

Respectfully submitted,

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